



PATENT  
Docket No. NB 2020.01

CERTIFICATE OF MAILING

I hereby certify that this paper or fee is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this date listed below.  
Dated: 5/19/05 Thao Pham

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application for:

Carlo BALLATORE et al.

Serial No.: 10/714,255

Filing Date: November 14, 2003

For: PEPTIDE DEFORMYLASE ACTIVATED  
PRODRUGS

Confirmation No.: 3615

Examiner: Rita J. Desai

Group Art Unit: 1625

INFORMATION DISCLOSURE STATEMENT

Mail Stop RCE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with 37 CFR §§ 1.97 and 198, the items identified in this Supplemental Information Disclosure Statement (IDS) are being brought to the attention of the Office. The items are listed on the attached forms PTO/SB/08a and PTO/SB/08b. The Examiner is requested to make these documents of record.

The items identified in this IDS may or may not be "material" pursuant to 37 CFR § 1.56. The submission thereof by Applicants is not to be construed as an admission that any such patent, publication or other information referred to therein is material or considered to be material (37 CFR § 1.97(h)), or even qualifies as "prior art" under 35 USC § 102 with respect to this invention unless specifically designated by Applicants as such.

**1. Timing of the Information Disclosure Statement:**

- This IDS is believed to be timely in that it is being submitted under 37 CFR § 1.97(b), that is (1) with the new patent application submitted herein (37 CFR § 1.97(a)); or (2) within three months of

the filing date of the application, which is not a continued prosecution application filed under § 1.53(d) or (3) within three months of entry of the national stage as set forth in 37 CFR § 1.491; or (4) before the mailing of a first Office action on the merits; or (5) before the mailing of a first Office action after filing a request for continued examination under § 1.114. Thus, no fee is required.

- However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this IDS as filed under 37 CFR § 1.97(c), if applicable, and charge the fee due under 37 CFR § 1.17(p) to the deposit account referenced below.
- However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this IDS as filed under 37 CFR § 1.97(c), if applicable, and a statement under 37 CFR § 1.97(e) is included below, thus no fee is required.
- This IDS is being submitted under 37 CFR § 1.97(c), that is after mailing of a first Office Action on the merits, but before a Final Action under 37 CFR § 1.113 or a Notice of Allowance under 37 CFR § 1.311.
  - The fee due under 37 CFR § 1.17(p) is submitted herewith.
  - The fee due under 37 CFR § 1.17(p) is being concurrently submitted with the filing of an electronic IDS submission. Thus, no additional fee is required.
  - A statement under 37 CFR § 1.97(e) is included below, thus no fee is required. In the event that this IDS is not received before a Final Action or a Notice of Allowance, then Applicant respectfully requests that the Office consider the filing of these papers to be submitted under 37 CFR § 1.97(d) and charge the fee due under 37 CFR § 1.17(p) to the deposit account below.
- This IDS is being submitted under 37 CFR § 1.97(d), that is after a Final Action under 37 CFR § 1.113 or a Notice of Allowance under 37 CFR § 1.311, but before payment of the issue fee. A statement under 37 CFR § 1.97(e) is included below. The fee due under 37 CFR § 1.17(p) is submitted herewith.
- This IDS is being submitted under 37 CFR § 1.97(i), that is after a Final Action under 37 CFR § 1.113 or a Notice of Allowance under 37 CFR § 1.311, but before payment of the issue fee.

**STATEMENT UNDER 37 CFR § 1.97(e):**

- No item contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS.
- No item contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this statement after making

reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this IDS.

**2. Copies of the Cited Items:**

- Copies of all of the items listed on the attached forms PTO/SB/08a and PTO/SB/08b are enclosed.
- Copies of only the following items listed on the attached forms PTO/SB/08a (Item Nos. \*) and PTO/SB/08b (Item Nos. \*) are enclosed.
- Copies of all items listed on the attached form PTO/SB/08a are not enclosed. See 37 CFR 1.98(a)(2)(i).
- Copies of the following documents listed in PTO/SB/08a (Item Nos. \*) and PTO/SB/08b (Item Nos. \*) are not supplied as they were previously cited by the Office or submitted in Information Disclosure Statements in related applications (Application No. \*, filed \*) and relied upon in this application for an earlier filing date under 35 USC § 120. See 37 CFR § 1.98(d). The Examiner is requested to make these documents of record.
- Copies of the following items listed on the attached forms PTO/SB/08a (Item Nos. \*) and PTO/SB/08b (Item Nos. \*) were cited in a foreign examination report in a related case. A copy of the search report and the cited references not already of record in this application are attached hereto.

**3. Concise Explanation of Relevance:**

- A concise explanation of relevance of the items listed on forms PTO/SB/08a and PTO/SB/08b is not given.
- A concise explanation of relevance of [some of] the items listed on forms PTO/SB/08a and PTO/SB/08b is in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references (copy attached).

**4. Related Applications:**

- Applicant(s) bring to the Office's attention the following related application(s):

**5. Conclusion:**

Citation of the above documents shall not be construed as:

1. an admission that the documents are necessarily prior art with respect to the instant invention;
2. a representation that a search has been made, other than as described above; and
3. an admission that the information cited herein is, or is considered to be, material to patentability as defined in § 1.56(b).

It is respectfully requested that the Examiner indicate consideration of the cited references by returning a copy of the attached forms PTO/SB/08a and PTO/SB/08b with initials or other appropriate marks. In the unlikely event that the transmittal letter is separated from this document and the U.S. Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-2518** referencing **7008422002**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: May 18, 2005

By:



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PATENT & TRADEMARK OFFICE  
SPECIAL FORMS FOR USE IN THE PATENT AND TRADEMARK OFFICE  
for form 1449B-PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

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of

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Complete if Known

Application Number	10/714,255
Filing Date	November 14, 2003
First Named Inventor	Carlo BALLATORE
Art Unit	1625
Examiner Name	Rita J Desai
Attorney Docket Number	NB 2020.01

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher city and/or country where published	T <sup>2</sup>
	1	APFEL, C. M. et al. "Hydroxamic acid derivatives as potent peptide deformylase inhibitors and antibacterial agents" <i>J. Med. Chem.</i> (2000) 43:2324-2331.	
	2	APFEL, C. M. et al. "Peptide deformylase as an antibacterial drug target: Assays for detection of its inhibition in <i>Escherichia coli</i> cell homogenates and intact cells" <i>Antimicrobial Agents and Chemotherapy</i> . (April 2001a) 45(4):1053-1057	
	3	APFEL, C.M. et al. "Peptide deformylase as an antibacterial drug target: Target validation and resistance development" <i>Antimicrobial Agents and Chemotherapy</i> (April 2001b) 45(4):1058-1064.	
	4	BECKER, A. et al. "Iron center, substrate recognition and mechanism of peptide deformylase" <i>Nat. Struc. Biol.</i> (December 1998) 5(12):1053-1058	
	5	CHAN, M. K. et al. "Crystal structure of the <i>Escherichia coli</i> peptidase deformylase" <i>Biochemistry</i> (1997) 36:13904-13909	
	6	CHEN, D. Z. et al. "Actinonin, a naturally occurring antibacterial agent, is a potent deformylase inhibitor" <i>Biochemistry</i> (2000) 39:1256-1262	
	7	CLEMENTS, J. M. et al. "Antibiotic activity and characterization of BB-3497, a novel peptide deformylase inhibitor" <i>Antimicrobial Agents and Chemotherapy</i> (February, 2001) 45(2):563-570	
	8	de GROOT, F. M. H. et al. "Synthesis and biological evaluation of 2'-carbamate-linked and 2'-carbonate-linked prodrugs of paclitaxel: selective activation by the tumor-associated protease plasmin" <i>J. Med. Chem.</i> (2000) 43:3093-3102	
	9	de GROOT, F.M.H. et al. "Synthesis and Biological Evaluation of Novel Prodrugs of Anthracyclines for Selective Activation by the Tumor-Associated Protease Plasmin" <i>J. Med. Chem.</i> (1999) 42(25):5277-5283	
	10	DUBOWCHIK, G. M. and R. A. Firestone "Cathepsin B-sensitive depeptide prodrugs. 1. A model study of structural requirements for efficient release of doxorubicin" <i>Bioor. &amp; Med. Chem. Letts.</i> (1998) 8:3341-3346	
	11	DURAND, D. J. et al. "Peptide aldehyde inhibitors of bacterial peptide deformylases" <i>Archives of Biochemistry and Biophysics</i> (July 15, 1999) 367(2):297-302	
	12	GIGLIONE, C. et al. "Identification of eukaryotic peptide deformylases reveals universality of N-terminal protein processing mechanisms" <i>The EMBO Journal</i> (2000) 19(21):5916-5929	
	13	GIGLIONE, C. et al. "Peptide deformylase as a target for new generation, broad spectrum antimicrobial agents" <i>Molecular Microbiology</i> (2000) 36(6):1197-1205	

Examiner's  
SignatureDate  
Considered

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. This information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Examiner Name	Rita J Desai
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	14	HAO, B. et al. "Structural basis for the design of antibiotics targeting peptide deformylase" <i>Biochemistry</i> (1999) 38(15):4712-4719	
	15	HU, Y.-J. et al. "H-phosphonate derivatives as novel peptide deformylase inhibitors" <i>Bioor. &amp; Med. Chem. Letts.</i> (1998) 8(18):2479-2482	
	16	HUNTINGTON, K. M. et al. "Synthesis and antibacterial activity of peptide deformylase inhibitors" <i>Biochemistry</i> (2000) 39(15):4543-4551	
	17	JAYASEKERA, M. M. K. et al. "Novel nonpeptidic inhibitors of peptide deformylase" <i>Archives of Biochem. and Biophys.</i> (September 15, 2000) 381(2):313-316	
	18	LACKEY, D. B. et al. "Enzyme-catalyzed therapeutic agent (ECTA) design: Activation of the antitumor ECTA compound NB 1011 by thymidylate synthase" <i>Biochem. Pharmacol.</i> (2001) 61:179-189	
	19	MEINNEL, T. "Vers une conception rationnelle de nouveaux agents antibactériens" <i>Path. Biol.</i> (Oct. 1999) 47(8):780-783	x
	20	MEINNEL, T. et al. "Methionine as translation start signal: A review of the enzymes of the pathway in <i>Escherichia coli</i> " <i>Biochemic</i> (1993) 75(12):1061-1075	
	21	RAGUSA S. et al. "Control of peptide deformylase activity by metal cations" <i>J. Mol. Biol.</i> (1998) 280:515-523	
	22	RAJAGOPALAN, P. T. R. and D. Pei "Oxygen-mediated inactivation of peptide deformylase" <i>Bio. Chem.</i> (August 28, 1998) 273(35):22305-22310	
	23	RAJAGOPALAN, P. T. R. et al. "Purification, characterization, and inhibition of peptide deformylase from <i>Escherichia coli</i> " <i>Biochem.</i> (1997) 36(45):13910-13918	
	24	WEI, Y. and D. Pei "Continuous spectrophotometric assay of peptide deformylase" <i>Analytical Biochem.</i> (1997) 250(1):29-34	
	25	WEI, Y. and D. Pei "Activation of antibacterial prodrugs by peptide deformylase" <i>Bioor. &amp; Med. Chem. Letts.</i> (2000a) 10(10):1073-1076	
	26	WEI, Y. et al. "Identification of a potent peptide deformylase inhibitor from a rationally designed combinatorial library" <i>J. Comb. Chem.</i> (2000b) 2(6):650-657	

Examiner's Signature	Date Considered
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